

Le Moyne College Institutional Review Board
REQUEST TO CHANGE AN APPROVED STUDY

All human subjects-related changes to IRB approved studies must be reviewed and approved by the IRB co-chairs prior to their implementation, unless immediate steps must be taken to protect subjects from imminent grave harm or risk. The IRB must be notified as soon as possible when unforeseen events necessitate an immediate change in procedure.

Please fill out all sections of this form completely. The IRB co-chairs will review the request and make a decision regarding the proposed changes. In rare cases, the co-chairs may decide that the proposed change requires full Board review before a decision can be made. The co-chairs will notify the researcher if the proposed change will require full Board review.

Date of Change Request:

Section I: Approved Study Information

Name of Investigator(s):

Form (*A, B, or C*):

IRB Application Number:

Title of Project (*as it appears on approved application*):

Date of Approval of Application (*or latest extension*):

Section II: Nature of the proposed change

- _____ 1. Change in the number of research subjects.
- _____ 2. Change in location or addition of a new site for recruiting subjects or for collecting data from your subjects. (Please submit a signed copy of a letter from the appropriate administrator or director of the site that gives you permission to conduct your research there).
- _____ 3. Change in procedure for recruiting subjects.
- _____ 4. Change in experimental methods (Change in what you will ask subjects to do).
- _____ 5. Other.

Section III: Explanation. In the space below, please provide the relevant details for the nature of the proposed change that you selected in Section II. Describe briefly the original plan, the change in plan, and your reasons for requesting the change. If subjects will be recruited or data will be collected at a conference or other public event, please provide the dates and location of the event. Use an additional page if necessary.

Signature

Date

Faculty Sponsor

Date